# **MEMORANDUM**

To:

Mr. Jim Buchert, Versar, Inc.

From:

Laura Casey, OPPT/NPCD/FOB

RE:

Technical Direction to Work Assignment 2-1

Subject:

Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation, Addendum II to Report: Exposure and Screening Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214 (April 11, 2005 Revision), dated August 18, 2006 associated with its Clariant Red Pigment Project

In this August 18, 2006 Addendum II, Clariant has provided an update to the September 16, 2005 Addenda to the Conceptual Exposure Model Report (August 2004 Revision), and Exposure and Screening Level Risk Assessment Report (April 11, 2005 Revision). In December 2005 Versar had provided comments on the September 2005 Addenda, which identified deficiencies in the exposure scenarios and assumptions. This updated August 2005 Addendum II was prepared to address Versar December 2005 comments as well as issues identified during an EPA/Versar conference call with Clariant. Region 1 will provide this Addendum II to Versar in hard copy via certified mail.

Please review this document for the following:

- Are the formulas provided in the Addendum II appropriate and are the proposed exposure/risk model input parameters appropriate based on the information provided? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.
- Referring back to the December 16, 2005 Memorandum from Versar to Laura Casey (EPA-HQ), has Clariant adequately addressed the issues/items identified in that memo?
- Based on its overall review of the document, does Versar have any additional recommendations regarding the adequacy of the assessment?

Due Date: Please turn the review of this document around by October 13, 2006. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.

Mike Teague/CLARIANT 09/08/2006 04:44 PM

Classification: Internal

To tisa.kimberly@epamail.epa.gov

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bcc

Subject RA Addendum II - August 2006 Revision

Kim -

Here is a revised Screening Risk Assessment Addendum that incorporates Clariant's response to Versar's last comments on the topic. I'll be following this email with two hardcopies of this document via FedEx to you.

We look forward to your response.

Best regards,

Mike

Mike Teague Clariant Corporation 4000 Monroe Road Charlotte, NC 28205 USA Office Phone: 704.331.7104 Cell Phone: 704.904.8707 FAX: 704.330.1528



Revised\_Addendum 8.18.06.pdf

# **ADDENDUM II TO REPORT:**

EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR
CARPET FIBER AND FOOD WRAP SCENARIOS
ASSOCIATED WITH PIGMENT RED 144/214
APRIL 11, 2005 REVISION

Prepared for Clariant Corporation 4000 Monroe Road Charlotte, NC 28205

Prepared by BBL Sciences

August 18, 2006

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# 1. Introduction

The April 11, 2005 report titled "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" contained a screening-level risk assessment for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of that assessment was to calculate acceptable, risk-based levels of tPCBs in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. In August 2005, new observations were added to input data and the report was updated via an addendum (BBL, 2005). Additional information consisted of a new maximum carpet concentration of 14.1 ppm (based on the re-analysis of ALTA LAB results), a new maximum food wrap concentration of 0.34 ppm, and a new packing tape concentration of 2.4 ppm (based on new analytical data). After the addendum was submitted to USEPA for comments, the agency indicated that the back-calculations of "safe" levels of PCBs in carpet were derived for exposure scenarios other than the absolute "worst-case" assumptions. For example, the maximum Retention Factor (RF) was set at 0.01. However, USEPA's contractor, Versar, commented that the calculation "does not present these carpet concentrations associated with the worst-case RF assumption," and that this "worst-case" should assume a RF of 1.0. The RF of 1.0 assumes that all of the PCBs in the carpet will volatilize into the indoor air. Implicit in this request is the assumption that there is an inexhaustible source of PCBs. In an actual house, carpet may not be replaced until its useful life span is over - about 10 years (Bigger and Bigger, 2004). Clearly, the assumption of an inexhaustible source will cause an unreasonable and unrealistic forecast of exposure and risk or hazard. Moreover, the USEPA suggested that although fully encapsulated into the polypropylene matrix, PCBs volatilize freely (i.e., the polypropylene shell is not an effective barrier to PCB volatilization) and entirely (i.e., 100% of the encapsulated mass is given off into the surrounding air). These assumptions also overstate exposure (and therefore risk) because the polypropylene matrix is likely to provide a significant barrier to any encapsulated PCBs, and empirical evidence shows that even "neat" PCBs (in a fluid form) volatilize very little (maximum of 5% Qi, 2003). Despite these concerns, we proceeded with calculations using the USEPA's requested assumptions of PCBs volatilization potential (and the minimum air exchange rate of 8.4 room air exchanges/day: USEPA, 1995) to show that, even using this unreasonable assumption, the back-calculated "safe" levels of PCBs in carpet are higher than those actually present (i.e. 14.1 ppm). However, calculations are performed for a finite mass of PCBs volatilizing into indoor air to maintain some realism in predictions.

The objective of the current Addendum is to update the April 11 report (and Addendum I; BBL, 2005) with the new data. This Addendum incorporates the abridged components of the original report to facilitate the discussion of the effects that new data may have on the outcome of the risk assessment.

# 2. Carpet Scenario

As indicated in the original report, the primary receptors for this analysis were young children (1 to 10 years old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. The extent of contact between children and carpet-borne constituents of interest was calculated via an exposure model. This model considered ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are briefly discussed below.

### 2.1 Exposure Model

### 2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard was as follows:

$$\frac{CNC_{carper}}{ED \cdot EF} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF} \left[ \left( \frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^{6} mg/kg} \right) + \left( \frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^{6} mg/kg} \right) + \left( \frac{1}{RfD} \cdot IHR \cdot \frac{1}{VF} \cdot RF \right) \right]$$

where.

CNC<sub>currer</sub>-risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg),

THQ-target hazard quotient (unitless),

BW-body weight (kg)

RfD-non-cancer reference dose (mg/kg BW/day),

 $AT_{nc}$ -non-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm<sup>2</sup>/day),

AF-dust adherence factor (mg/cm<sup>2</sup>),

DERM-dermal absorption factor (unitless),

IHR-inhalation rate (m<sup>3</sup>/day),

VF-volatilization factor (m3/kg), and

RF-retention factor (unitless).

The volatilization factor (VF) used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing a carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning  $(K_{Sd})$  were as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \log VP}$$
 Equation 2

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g}$$
 Equation 3

substituting Equation 3 into Equation 2 and solving for Myields,

$$M = (d_w \cdot 10^{3.82 \cdot 0.62 \log 1/P} \cdot C_g)$$
 Equation 4

where,

 $k_c$ -adsorption coefficient (m/hr),  $k_d$ -desorption coefficient (m/hr),  $d_{ic}$ -carpet thickness (m), VP-vapor pressure (Pa),

 $C_g$ -acceptable concentration of PCBs in air from Equation 1 and 9 (mg/m<sup>3</sup>), and M-mass of PCBs per area of carpet (mg/m<sup>2</sup>).

To express M on carpet weight basis ( $M_{cw}$ ; mg/kg), this parameter can be divided by carpet face weight (FW; kg/m<sup>2</sup>) such that

$$M_{ew} = \frac{(d_w \cdot 10^{3.82 - 0.62 \log VP} \cdot C_g)}{FW}$$
 Equation 5

Furthermore, in realistic conditions of a normal house, ventilation is provided to maintain proper air quality. Therefore, the  $M_{\rm cw}$  term must allow for a dilution factor (AE; unitless) to avert modeling unrealistically high concentrations. Thus, Equation 5 is modified to

$$M_{cw} = \frac{d_w \cdot 10^{3.82 - 0.62 \log 17} \cdot C_g \cdot AE}{FW'}$$
 Equation 6

The volatilization factor (VF;  $m^3/kg$ ) was derived by dividing  $M_{cw}$  by the air concentration term  $C_g$  (Equation 7). The VF was inserted into Equation 1 to calculate an acceptable carpet concentration attributable to tPCB volatilization.

$$VF = \frac{M_{ew}}{C_g} = \frac{(d_w \cdot 10^{3.82 \cdot 0.62 \log 1T} \cdot AE)}{FW}$$
 Equation 7

Given that  $C_g$  is calculated in Equation 1 and 9 using the inhalation exposure assumptions, VF was inserted in these equations to derive an acceptable concentration in carpet fiber ( $M_{ev}$ ; mg/kg).

$$VF*C_g = M_{cu}$$
 Equation 8

#### 2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Curped} = \frac{TR \cdot BW \cdot AT_{e}}{ED \cdot EF \left[ \left( \frac{CSF \cdot IR \cdot BioAF}{10^{6} mg/kg} \right) + \left( \frac{CSF \cdot SA \cdot AF \cdot DERM}{10^{6} mg/kg} \right) + \left( \frac{CSF \cdot IHR \cdot \frac{1}{VF} \cdot RF}{VF} \right) \right]}$$

where,

CC<sub>Curpet</sub>-risk-based concentration in carpet associated with 1 x 10<sup>-6</sup> cancer risk (mg/kg),

TR-target cancer risk,

BW-body weight (kg),

CSF-cancer slope factor (mg/kg BW/day)<sup>-1</sup>,

 $AT_c$ -cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm²/day),

AF-dust adherence factor (mg/cm<sup>2</sup>),

IHR-inhalation rate (m3/day),

DERM-dermal uptake factor (unitless),

VF-volatilization factor (m3/kg), and

RF-retention factor (unitless).

### 2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources, including USEPA guidance documents, published literature, the internet, and Clariant's database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

#### 2.2.1 Body Weight

The receptor of interest in the carpet scenario was a young child who is expected to be in direct contact with carpeted surfaces as a result of normal daily activities such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age was 21.8 kg (USEPA, 2000) (Table 1).

### 2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate was set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the maximum exposure duration in this assessment was assumed to be 10 years. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days) (USEPA 1997, 2002) (Table 1). The maximum exposure frequency was set to the default of 350 days per year (USEPA 1997, 2002) and the event frequency at one event per day. Note that the RF was set to vary from 0.0001 to 1. As a result, exposure frequency was set to vary for each RF scenario as the finite mass of PCBs volatilizes from carpet at a RF-dependent rate (Table 1). The method to estimate the times of total exhaustion of PCBs from carpet via volatilization and subsequent clearance from a hypothetical room for each RF was based on the flux-based approach of Bennett and Furtaw (2004) for indoor residential fate modeling of pesticides on carpet. This methodology is described below.

### 2.2.3 PCB Mass Transfer Rate

The flux-based transfer of PCBs from carpet into air was presented and used by BBL in previous assessments of PCB volatilization. Please note that this model was used as a surrogate for a yet unknown/undeveloped model of PCB vapor diffusion in carpet.

The mass-transfer rate (MTR) algorithm is as follows:

$$MTR_{PCB} = SA_{Carpet} \times \frac{D_{Air}}{T_{Carpet}} \left( \frac{VP_{PCB}}{R_C \times t_{Air}} \right)$$
 Equation 10

where,

MTR<sub>PCB</sub> - mass transfer rate (mg PCB/room-day),

SA<sub>Carper</sub> - carpet surface area (m<sup>2</sup>),

 $D_{Air}$  - diffusivity of PCB in air (m<sup>2</sup>/day),

 $T_{Carpet}$  - carpet thickness (m),

VP<sub>PCB</sub> - vapor pressure of PCB 44/70 mixture (Pa), Rc - ideal gas constant (Pa x m³/mol x K), and

 $t_{Alir}$  - ambient air temperature (K).

In effect, this relationship estimates the quantity of PCBs that volatilize from the carpet surface into the room on a daily basis. The model was parameterized using the input variables presented in Table 1. The main assumptions are:

- 1. PCBs volatilize freely. This causes the conceptual model to assume that the entire mass of PCBs contained in the carpet will volatilize into air. This implies that:
  - a. PCBs are found on the exterior surfaces of carpet fibers rather than encapsulated in the polypropylene shell (as is the case in actual carpet), and
  - b. PCBs potentially present in carpet will volatilize into air at a maximum rate until depleted rather than at a reduced rate (due to its semi-volatile nature and encapsulation process).
- The PCB concentration in carpet is at the maximum. The assessment uses the highest concentrations of PCBs in carpet rather than a sales-volume, carpet concentration-based measure of central tendency.
- 3. Lowest recommended room air exchange rates. It is assumed that the air exchange in the model room is the lowest recommended by the USEPA (i.e. 8.4 air exchanges/day). However, a standard room in an actual house may experience far greater ventilation rates.
- 4. Carpet synthesized on-site. The assumption is that the carpet is installed the moment it is manufactured, and the exposure to the resident begins immediately. In reality, carpets may not be installed for months after they have left the production facility, and the family may not be in the house during and immediately after carpet installation.
- Vapor Pressure of PCBs. The PCBs are assumed to volatilize from a surface of an inert substance whose vapor pressure = 0. Therefore, the vapor pressure of PCBs is set to equal the vapor pressure for pure PCBs (i.e. PCB 44/70 mixture).

These assumptions are consistent with the USEPA's desire to examine the "worst-case" exposure scenario.

Under the assumption of PCBs volatilizing as a uniform chemical from an inert surface, the maximum flux rate of PCBs from the carpet surface, estimated by Equation 10, is 668 mg PCB/room-day (at RF=1). The flux rates for RF equal to 0.01, 0.005, 0.001, and 0.0001 are 6.68, 3.34, 0.67, and 0.067 mg PCB/room-day, respectively. Given that the total mass of PCBs in a hypothetical room (25 m²) is 599 mg PCB (i.e. 14.1 mg PCB/kg x 1.7 kg carpet/m² x 25 m²), the available mass will volatilize completely within 22 hours at RF=1, 89 days at RF=0.01, 179 days at RF=0.005, 894 days at RF=0.001, and 8,969 days at RF=0.0001 (set to a maximum of 10 years or 3,650 days). Because there will be some tag between the point in time when the last of PCBs volatilize into air and when the air concentration in a room reaches zero (due to ventilation), we extended the potential duration to airborne PCBs by several days (based on air concentration calculations at ventilation rate of 8.4 exchanges/day).

Therefore, the final exposure frequencies (EFs) at given RF (and exposure durations) were:

RF EF (days/ye		
1.0	3 for 1 year	
0.01	100 for 1 year	
0.005	180 for 1 year	
0.001	350 for 2.47 years	
0.0001	350 for 10 years	

These temporal data were entered into Equations 1 and 9 (for every potential exposure route) to calculate the "safe" concentrations of PCBs in carpet for each non-cancer and cancer RF scenario.

### 2.2.4 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario was assumed to be via the incidental ingestion of carpet fibers/dust as a result of the mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, an average dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1). A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via digestive tract activities. This factor was set to range from 1% to 100% (Table 1) due to uncertainty as to its real empirical magnitude.

However, please note that oral bioavailability studies show that it is very unlikely that the bioavailability reaches the higher end of the range presented here. Please see the discussion below.

## 2.2.5 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m<sup>3</sup>/day, which is the average estimate for children ranging in age from 1 to 10 years old (USEPA, 2000) (Table 1). The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m, and face weight was set to 1,700,000 mg/m² (1.7 kg/m²) based on information obtained from the carpet industry (RPA, 2004; Carpet USA, 2004) (Table 1). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, an air dilution factor (AE) was added to Equation 6. The value of that factor was 8.4 air exchanges per day based on the minimum ventilation rate required by USEPA.

### 2.2.6 Dermai Uptake Parameters

According to the USEPA (2000), the skin surface area available for contact during warm-weather play of children, with 32% of the total skin surface area exposed, is 2,763 cm²/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact, was estimated at 0.00724 mg/cm² (USEPA, 2000). This value reflects soil adherence for children: post-activity; indoors; and on hands, arms, legs, and feet. An assumption was made that carpet fibers behave similarly to soil particles. The USEPA's default value for the dermal absorption factor for tPCBs in soil of 14% (USEPA, 2001) was adopted as the default value in this screening-level risk assessment.

#### 2.3 Hazard and Risk Reference Values

The non-cancer reference dose for PCBs was 0.00002 mg/kg/day (reference dose for Aroclor 1254; USEPA, 2002). The cancer slope factor was 0.07 (mg/kg/day)<sup>-1</sup> and it represented the lowest risk and persistence category recommended by the USEPA (2002). The target risk used in the calculation was the low end of the USEPA's "acceptable risk range" of I in 1 million exposed individuals (1 x 10<sup>-6</sup>) (USEPA, 1996, 1997, 2000) (Table 1). The target hazard quotient was set to 1.

#### 2.4 Results and Discussion

For exposures associated with non-cancer hazard, the combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber ranging from approximately 8 to 671 mg tPCBs/kg, depending on the magnitude of the bioavailability and retention factors (Table 2). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in 1 million cancer risk range from 39 to 33,575 mg/kg (Table 2). Comparing the tPCB concentrations estimated in the finished product (carpet; 14.1 mg/kg) to the results from the current assessments suggests that, even at 100% bioavailability and 0% retention, it is highly unlikely that any cancer risk responses will be triggered. Inspection of the results table for non-cancer hazard calculations reveals that the estimated maximum concentration in the final product (14.1 mg/kg) exceeds the acceptable concentrations under only two exposure conditions: when the oral bioavailability is 100% and RFs are 0.001 and 0.0001. Because 100% oral bioavailability is unlikely in actual exposures, these two scenarios should not be of concern in risk-making decisions. This statement is supported by empirical evidence from a recent soil mobilization study of Oomen et al. (2000), who found that the maximum proportion of PCBs that can be digested from PCB-laden soil by a human gut is 40%. Furthermore, the authors indicate that this bioaccessible fraction may not be entirely absorbed by the gut. Also, unlike soil, polypropylene fibers encapsulate PCBs reducing the bioavailability even further. Even if one was to assume 100% absorption of the bioaccessible fraction (i.e. bioavailability factor = 40%) the allowable concentration of PCBs in carpet would be well above the maximum concentration of 14.1 mg/kg. According to our calculations, the absorption factor (a product of bioaccessibility and intestinal absorption) would have to be more than 53% in order for the allowable carpet concentrations to drop below that threshold.

There is one technical point to note in Table 2. The inclusion of the volatilization/source depletion factor actually has its most significant influence on the estimated dose from the ingestion pathway. As a result, the lowest RFs (0.001 and 0.0001) result in the lowest risk-based concentration. This is because the PCBs remain in the carpet longer so that they can be ingested via the carpet dust. In effect, as the RF decreases, the PCBs persist in the carpet fiber longer and the impact of the RF diminishes. This effect can be seen in Table 2 where the acceptable tPCB concentrations at RF=0.001 and RF=0.0001 are almost identical. In consequence, the exposure, dose, and ultimately, the risk are attributed almost entirely to the ingestion route of exposure. In contrast, at higher RFs (up to 1.0) the PCBs are not retained in the carpet for extended periods of time, and therefore, while the concentration in the air is higher under this condition, it is only for a very short period of time. Therefore, the exposure may be higher, but for a shorter period of time.

Please note that the use of the results of this analysis for risk management decision making should be done with caution because of the level of the uncertainty associated with the estimate of the maximum carpet concentration, retention factor, the quantity of ingested fiber, and oral bioavailability. These factors likely overstate exposure (and therefore risk) for several reasons, not the least of which is the probability that the polypropylene matrix is likely to provide a significant barrier to any encapsulated PCBs. Therefore, given the extensive level of conservatism and the low likelihood of PCBs being 100% bioavailable, it is doubtful that children exposed to carpet would experience any adverse health effects.

# 3. Conclusions

Despite high-end exposure assumptions, the concentrations determined to be within the USEPA's acceptable cancer risk range were well above the maximum concentration of tPCBs estimated in the carpet. Two conservative exposure scenarios for non-cancer hazards (i.e., 100% oral bioavailability at RF=0.001 and RF=0.0001) indicated that the allowable carpet concentrations may be lower than those estimated in the final product. However, given the redundant conservatism built into the assessment (e.g., the low likelihood of 100% oral bioavailability), it is likely that the risks and hazards are substantially overstated. Therefore, the current analysis suggests that there was no unacceptable risk, and that there are no obvious public health concerns associated with the pigments in carpet.

# 4. References

- Clariant (Confidential Business Information undated). Exposure and Toxicological Assessment for PCBs in Multilayered Food Packaging Film. Clariant reviewed document with USEPA in December, 2003.
- 48 Fed. Reg. 50846, November 1, 1983. Inadvertent production of tPCBs in the synthesis of dyes.
- 62 Fed. Reg. 9365, March 3, 1997. Department of Health and Human Services. Food and Drug Administration.
- 21CFR Part 178. Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers. Final Rule.
- BBL (Blasland, Bouck, and Lee). 2004. Conceptual Exposure Model and Preliminary Assessment for End Users of Pigment Red 144 and 214. Blasland Bouck and Lee, August 31, 2004.
- BBL. 2005. Addendum to Report: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, April 11, 2005. Blasland Bouck and Lee, August 4, 2005.
- Bennet, D.H. and E.J. Furtaw. 2004. Fugacity-based indoor residential pesticide fate model. Environ. Sci. Technol. 38: 2142-2152.
- Bigger, A.S. and L.B. Bigger. 2004. Carpet considerations. A new generation of carpet and the equipment to keep it clean gives more cost-effective options. www.facilitiesnet.com. Last accessed November, 2004.
- Carpet USA. 2004. Inventory of carpets available for sale. www.carpet-use.com. Last accessed November, 2004.
- Hack, A. and F. Selenka. 1996. Mobilization of PAH and PCB from contaminated soil using a digestive tract model. Toxicol. Lett. 88: 199-210.
- Long, C.M., H.H. Suh, and P. Koutrakis. 2000. Characterization of indoor particle sources using continuous mass and size monitors. J. Air Waste Manage. Assoc. 50: 1236-1250.
- MacKay, D., W.Y. Shiu, and K.C. Ma. 1992. Illustrated Handbook of Physical-Chemical Properties and Environmental Fate for Organic Chemicals. Volume I. Lewis Publishers, Chelsea, USA. 697 pp.
- Mayes, B.A., G.L. Brown, F.J. Mondello, K.W. Holtzclaw, S.B. Hamilton, and A.A. Ramsey. 2002. Dermal absorption in rhesus monkeys of polychlorinated biphenyls from soil contaminated with Aroclor 1260. Regul. Toxicol. Pharmacol. 35: 289-295.
- Moya, J.B.S., C.F. Bearer, and R.A. Etzel. 2004. Children's behavior and physiology and how it affects exposure to environmental contaminants. Pediatrics 113: 996-1006.
- Murray, D.M. and D.E. Burmaster. 1995. Residential air exchange rates in the United States: Empirical and estimated parametric distributions by season and climatic region. Risk Analysis 15: 459-465.
- Oomen, A., A. Sips, J. Groten, D. Sijm, and J. Tolls. 2000. Mobilization of PCBs and Lindane from soil during in vitro digestion and their distribution among bile salt micelles and proteins of human digestive fluid and the soil. Environ. Sci. Technol. 34: 297-303.

4-1

- Qi, Shuang. 2003. PCB Volatilization from Sediments. PhD Thesis, University of Cincinnati, Department of Environmental Engineering. 144p
- RPA (Radiant Panel Association). 2004. Carpet and cushion. Technical notes. Radiant Panel Association. www.radiantpanelassociation.org. Last accessed November, 2004.
- Ruby, M.V., K.A. Fehling, D.J. Paustenbach, B.D. Landenberger, and M.P. Holsapple. 2002. Oral bioaccessibility of dioxins/furans at low concentrations (50-350 ppt toxicity equivalent) in soil. Environ. Sci. Technol. 36: 4905-4911.
- Smiciklas-Wright, H., D.C. Mitchell, S.J. Mickle, A.J. Cook, and J.D. Goldman. 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, pre-publication version, 252 pp.
- USEPA (United States Environmental Protection Avency). 1989. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A). U.S. Environmental Protection Agency Office of Solid Waste and Emergency Response, Toxics Integration Branch, Washington, DC. EPA/540/1-89/002.
- USEPA (United States Environmental Protection Avency). 1996. PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. EPA/600/P-96/001.
- USEPA (United States Environmental Protection Avency). 1997. Exposure Factors Handbook. General Factors. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. EPA/600/P-95/002Fa.
- USEPA (United States Environmental Protection Avency). 2000. Child-Specific Exposure Factors Handbook. United States Environmental Protection Agency, Office of Research and Development. NCEA-W-0853.
- USEPA (United States Environmental Protection Avency). 2001. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites, Inerim Guidance. OSWER 9355.4-24.
- USEPA (United States Environmental Protection Avency). 2002. Region 9 PRGs Table 2002 Update. United States Environmental Protection Agency, Region 9, San Francisco, CA.
- Won, D.Y., R.L. Corsi, and M. Rynes. 2000. New indoor carpet as an adsorptive reservoir for volatile organic compounds. Environ. Sci. Technol. 34: 4139-4198.

# 5. Tables

Table 1. Exposure and Risk Model Input Parameters

Parameter	Value	Source
General	<del></del>	
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 10 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (maximum; yrs)	10	Bigger and Bigger (2004)
Exposure Duration (years)	i to 10	Calculated <sup>1</sup>
Exposure Frequency (days/year)	3 to 350	Calculated'; USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging time: non-cancer (maximum; days)	365 to 3,650	Calculated; USEPA (1997; 2002)
Averaging time: cancer (days)	25,550	USEPA (1997; 2002)
Maximum PCB carpet concentration (mg PCB/kg carpet)	14.1	Estimated; Clariant
Total PCB mass (mg) in a hypothetical room	599	Calculated
Ingestion		
Dust (soil) ingestion rate (children; rng dust/day)	55	Moya et al. (2004)
Bioavailability of PCBs in fiber (%)	1, 5, 10, 50, and 100	Assumption
Inhalation		
Inhalation rate (1 to 10 yrs old; m³/day)	10.4	USEPA (2000)
Complete air exchange rate (1/day)	8.4	USEPA (1995)
Vapor pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Room volume (Hypothetical; m³)	50	Assumption
Floor area (Hypothetical; m²)	25	Assumption
Carpet thickness (m)	0.01286	RPA (2004)
Carpet area mass (face weight; kg/m²)	1.7	Carpet USA (2004)
Room temperature (K)	293	Assumption
Molecular weight of air (g/mol)	29	Calculated
Molecular weight of PCB (g/mol)	292	Calculated
Atmospheric pressure (atm)	1	Assumption
Molar volume of air (cm³/mol)	20.1	Calculated
Molar volume of PCB (cm³/mol)	268	Calculated
Diffusivity of PCB in air (m²/day)	0.416	Calculated; Fuller et al. (1966) <sup>2</sup>
Vapor pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Ideal gas constant (Pa x m³/mot x K)	8.314	Constant
Retention factor (unitless)	0.0001 to 1	Assumption

Parameter	Value	Source	
Dermal			
Dust adherence factor for children post-activity indoors on hands, arms, legs, and feet (mg/cm²)	0.00724	USEPA (2000)	
Contact skin surface area during warm-weather play with 32% skin exposed (cm²/day)	2,763	USEPA (2000)	
Dermal uptake factor	0.14	USEPA (2001)	
Hazard and Risk Reference Values			
Target hazard quotient	I	USEPA (1997; 2002)	
Non-cancer reference dose (mg/kg BW/day)	0.00002	USEPA (2002)	
Cancer slope (mg/kg BW/day) <sup>-1</sup>	0.07	USEPA (2002)	
Target cancer risk	1 x 10 <sup>-6</sup>	USEPA (1997; 2002)	
Target lifetime average daily dose (mg/kg BW/day)	0.000014	Equal to acceptable risk over cancer slope	

 $<sup>\</sup>begin{array}{l} ^{1}Retention\ factor-dependent \\ ^{2}D_{Air} = 10^{13}*(t_{Air}^{1.75}*(1/M_{Air}+1/M_{PCB})^{0.5})/P(V_{Air}^{-0.33}+V_{PCB}^{-0.33})^{2} \end{array}$ 

Table 2. August 2006 Revised Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber for Child Non-Cancer and Cancer Risk Scenarios Assuming Complete Volatilization from Carpet Surface and Finite PCB mass

Oral	Acceptable Concentration in Carpet Fiber (mg tPCB/kg)  Retention Factor					
Bioavailability						
Factor	0.0001	0.001	0.005	0.01	1	
		Non-Cancer H	azard		<u></u>	
0.01	135.4	133	237	387	671	
0.05	81.8	80.9	149	252	653	
0,10	54.7	54.3	102	176	632	
0.50	15.0	15.0	28.8	51.2	501	
1.00	7.87 <sup>a</sup>	7.86ª	15.2	27.2	398	
		Cancer Ri	sk		•	
0.01	677	2,686	11,855	19,374	33,575	
0.05	409	1,636	7,456	12,616	32,665	
0.10	274	1,099	5,094	8,785	31,595	
0.50	75.0	303	1,441	2,562	25,034	
1.00	39.3	159	760	1,359	19,875	

<sup>&</sup>lt;sup>a</sup>The result is 14.2 mg/kg for oral bioavailability factor of 0.53



# Mike.Teague@clariant.com 09/08/2006 04:44 PM

To Kimberly Tisa/R1/USEPA/US@EPA

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bcc

Subject RA Addendum II - August 2006 Revision

Kim -

Here is a revised Screening Risk Assessment Addendum that incorporates Clariant's response to Versar's last comments on the topic. I'll be following this email with two hardcopies of this document via FedEx to you.

We look forward to your response.

Best regards,

Mike

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# ADDENDUM II TO REPORT:

EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR
CARPET FIBER AND FOOD WRAP SCENARIOS
ASSOCIATED WITH PIGMENT RED 144/214
APRIL 11, 2005 REVISION

Prepared for Clariant Corporation 4000 Monroe Road Charlotte, NC 28205

Prepared by BBL Sciences

August 18, 2006

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# 1. Introduction

The April 11, 2005 report titled "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" contained a screening-level risk assessment for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of that assessment was to calculate acceptable, risk-based levels of tPCBs in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. In August 2005, new observations were added to input data and the report was updated via an addendum (BBL, 2005). Additional information consisted of a new maximum carpet concentration of 14.1 ppm (based on the re-analysis of ALTA LAB results), a new maximum food wrap concentration of 0.34 ppm, and a new packing tape concentration of 2.4 ppm (based on new analytical data). After the addendum was submitted to USEPA for comments, the agency indicated that the back-calculations of "safe" levels of PCBs in carpet were derived for exposure scenarios other than the absolute "worst-case" assumptions. For example, the maximum Retention Factor (RF) was set at 0.01. However, USEPA's contractor, Versar, commented that the calculation "does not present these carpet concentrations associated with the worst-case RF assumption," and that this "worst-case" should assume a RF of 1.0. The RF of 1.0 assumes that all of the PCBs in the carpet will volatilize into the indoor air. Implicit in this request is the assumption that there is an inexhaustible source of PCBs. In an actual house, carpet may not be replaced until its useful life span is over - about 10 years (Bigger and Bigger, 2004). Clearly, the assumption of an inexhaustible source will cause an unreasonable and unrealistic forecast of exposure and risk or hazard, Moreover, the USEPA suggested that although fully encapsulated into the polypropylene matrix, PCBs volatilize freely (i.e., the polypropylene shell is not an effective barrier to PCB volatilization) and entirely (i.e., 100% of the encapsulated mass is given off into the surrounding air). These assumptions also overstate exposure (and therefore risk) because the polypropylene matrix is likely to provide a significant barrier to any encapsulated PCBs, and empirical evidence shows that even "neat" PCBs (in a fluid form) volatilize very little (maximum of 5% Qi, 2003). Despite these concerns, we proceeded with calculations using the USEPA's requested assumptions of PCBs volatilization potential (and the minimum air exchange rate of 8.4 room air exchanges/day; USEPA, 1995) to show that, even using this unreasonable assumption, the back-calculated "safe" levels of PCBs in carpet are higher than those actually present (i.e. 14.1 ppm). However, calculations are performed for a finite mass of PCBs volatilizing into indoor air to maintain some realism in predictions.

The objective of the current Addendum is to update the April 11 report (and Addendum I; BBL, 2005) with the new data. This Addendum incorporates the abridged components of the original report to facilitate the discussion of the effects that new data may have on the outcome of the risk assessment.

# 2. Carpet Scenario

As indicated in the original report, the primary receptors for this analysis were young children (1 to 10 years old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. The extent of contact between children and carpet-borne constituents of interest was calculated via an exposure model. This model considered ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are briefly discussed below.

# 2.1 Exposure Model

# 2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard was as follows:

$$CNC_{Corpel} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF \left[ \left( \frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^6 mg/kg} \right) + \left( \frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^6 mg/kg} \right) + \left( \frac{1}{RfD} \cdot IHR \cdot \frac{1}{VF} \cdot RF \right) \right]}$$

where,

CNC<sub>Carpet</sub>-risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg),

THQ-target hazard quotient (unitless),

BW-body weight (kg)

RfD-non-cancer reference dose (mg/kg BW/day),

AT<sub>nc</sub>-non-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm²/day),

AF-dust adherence factor (mg/cm2),

DERM-dermal absorption factor (unitless),

IHR-inhalation rate (m3/day),

VF-volatilization factor (m3/kg), and

RF-retention factor (unitless).

Equation 1

The volatilization factor (VF) used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing a carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning ( $K_{SA}$ ) were as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \log VP}$$
 Equation 2

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g}$$
 Equation 3

substituting Equation 3 into Equation 2 and solving for M yields,

$$M = (d_w \cdot 10^{3.82 - 0.62 \log^{VP}} \cdot C_g)$$
 Equation 4

where,

 $k_s$ -adsorption coefficient (m/hr),  $k_d$ -desorption coefficient (m/hr),  $d_w$ -carpet thickness (m), VP-vapor pressure (Pa),  $C_g$ -acceptable concentration of PCBs in air from Equation 1 and 9 (mg/m³), and M-mass of PCBs per area of carpet (mg/m²).

To express M on carpet weight basis ( $M_{cw}$ ; mg/kg), this parameter can be divided by carpet face weight (FW;  $kg/m^2$ ) such that

$$M_{cw} = \frac{(d_w \cdot 10^{3.82 - 0.62 \log VP} \cdot C_g)}{FW}$$
 Equation 5

Furthermore, in realistic conditions of a normal house, ventilation is provided to maintain proper air quality. Therefore, the  $M_{\rm cw}$  term must allow for a dilution factor (AE; unitless) to avert modeling unrealistically high concentrations. Thus, Equation 5 is modified to

$$M_{cw} = \frac{d_w \cdot 10^{3.82 - 0.62 \log VP} \cdot C_g \cdot AE}{FW}$$
 Equation 6

The volatilization factor (VF;  $m^3/kg$ ) was derived by dividing  $M_{cw}$  by the air concentration term  $C_g$  (Equation 7). The VF was inserted into Equation 1 to calculate an acceptable carpet concentration attributable to tPCB volatilization.

$$VF = \frac{M_{cw}}{C_g} = \frac{(d_w \cdot 10^{3.82 - 0.62 \log VP} \cdot AE)}{FW}$$
 Equation 7

Given that  $C_g$  is calculated in Equation 1 and 9 using the inhalation exposure assumptions, VF was inserted in these equations to derive an acceptable concentration in carpet fiber ( $M_{cw}$ ; mg/kg).

$$VF*C_g = M_{cw}$$
 Equation 8

#### 2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Compet} = \frac{TR \cdot BW \cdot AT_{c}}{ED \cdot EF \left[ \left( \frac{CSF \cdot IR \cdot BioAF}{10^{6} mg/kg} \right) + \left( \frac{CSF \cdot SA \cdot AF \cdot DERM}{10^{6} mg/kg} \right) + \left( \frac{CSF \cdot IHR \cdot \frac{1}{VF} \cdot RF}{10^{6} mg/kg} \right) \right]}$$

where,

CC<sub>Carpet</sub>-risk-based concentration in carpet associated with 1 x 10<sup>-6</sup> cancer risk (mg/kg),

TR-target cancer risk,

BW-body weight (kg),

CSF-cancer slope factor (mg/kg BW/day)-1,

 $AT_c$ -cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm<sup>2</sup>/day),

AF-dust adherence factor (mg/cm2),

IHR-inhalation rate (m3/day),

DERM-dermal uptake factor (unitless),

VF-volatilization factor (m3/kg), and

RF-retention factor (unitless).

### 2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources, including USEPA guidance documents, published literature, the internet, and Clariant's database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

# 2.2.1 Body Weight

The receptor of interest in the carpet scenario was a young child who is expected to be in direct contact with carpeted surfaces as a result of normal daily activities such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age was 21.8 kg (USEPA, 2000) (Table 1).

# 2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate was set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the maximum exposure duration in this assessment was assumed to be 10 years. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days) (USEPA 1997, 2002) (Table 1). The maximum exposure frequency was set to the default of 350 days per year (USEPA 1997, 2002) and the event frequency at one event per day. Note that the RF was set to vary from 0.0001 to 1. As a result, exposure frequency was set to vary for each RF scenario as the finite mass of PCBs volatilizes from carpet at a RF-dependent rate (Table 1). The method to estimate the times of total exhaustion of PCBs from carpet via volatilization and subsequent clearance from a hypothetical room for each RF was based on the flux-based approach of Bennett and Furtaw (2004) for indoor residential fate modeling of pesticides on carpet. This methodology is described below.

# 2.2.3 PCB Mass Transfer Rate

The flux-based transfer of PCBs from carpet into air was presented and used by BBL in previous assessments of PCB volatilization. Please note that this model was used as a surrogate for a yet unknown/undeveloped model of PCB vapor diffusion in carpet.

The mass-transfer rate (MTR) algorithm is as follows:

$$MTR_{PCB} = SA_{Carpet} imes rac{D_{Air}}{T_{Carpet}} \left( rac{VP_{PCB}}{R_C imes t_{Air}} 
ight)$$
 Equation 10

where,

 $MTR_{PCB}$  – mass transfer rate (mg PCB/room-day),

 $SA_{Carpet}$  - carpet surface area (m<sup>2</sup>),  $D_{dir}$  - diffusivity of PCB in air (m<sup>2</sup>/day),

- carpet thickness (m),  $T_{Carpet}$ 

 $VP_{PCB}$ - vapor pressure of PCB 44/70 mixture (Pa), Rc- ideal gas constant (Pa x m<sup>3</sup>/mol x K), and

 ambient air temperature (K).  $t_{Air}$ 

In effect, this relationship estimates the quantity of PCBs that volatilize from the carpet surface into the room on a daily basis. The model was parameterized using the input variables presented in Table 1. The main assumptions are:

- 1. PCBs volatilize freely. This causes the conceptual model to assume that the entire mass of PCBs contained in the carpet will volatilize into air. This implies that:
  - a. PCBs are found on the exterior surfaces of carpet fibers rather than encapsulated in the polypropylene shell (as is the case in actual carpet), and
  - b. PCBs potentially present in carpet will volatilize into air at a maximum rate until depleted rather than at a reduced rate (due to its semi-volatile nature and encapsulation process).
- 2. The PCB concentration in carpet is at the maximum. The assessment uses the highest concentrations of PCBs in carpet rather than a sales-volume, carpet concentration-based measure of central tendency.
- 3. Lowest recommended room air exchange rates. It is assumed that the air exchange in the model room is the lowest recommended by the USEPA (i.e. 8.4 air exchanges/day). However, a standard room in an actual house may experience far greater ventilation rates.
- 4. Carpet synthesized on-site. The assumption is that the carpet is installed the moment it is manufactured, and the exposure to the resident begins immediately. In reality, carpets may not be installed for months after they have left the production facility, and the family may not be in the house during and immediately after carpet installation.
- 5. Vapor Pressure of PCBs. The PCBs are assumed to volatilize from a surface of an inert substance whose vapor pressure = 0. Therefore, the vapor pressure of PCBs is set to equal the vapor pressure for pure PCBs (i.e. PCB 44/70 mixture).

These assumptions are consistent with the USEPA's desire to examine the "worst-case" exposure scenario.

Under the assumption of PCBs volatilizing as a uniform chemical from an inert surface, the maximum flux rate of PCBs from the carpet surface, estimated by Equation 10, is 668 mg PCB/room-day (at RF=1). The flux rates for RF equal to 0.01, 0.005, 0.001, and 0.0001 are 6.68, 3.34, 0.67, and 0.067 mg PCB/room-day, respectively. Given that the total mass of PCBs in a hypothetical room (25 m²) is 599 mg PCB (i.e. 14.1 mg PCB/kg x 1.7 kg carpet/m² x 25 m²), the available mass will volatilize completely within 22 hours at RF=1, 89 days at RF=0.01, 179 days at RF=0.005, 894 days at RF=0.001, and 8,969 days at RF=0.0001 (set to a maximum of 10 years or 3,650 days). Because there will be some lag between the point in time when the last of PCBs volatilize into air and when the air concentration in a room reaches zero (due to ventilation), we extended the potential duration to airborne PCBs by several days (based on air concentration calculations at ventilation rate of 8.4 exchanges/day).

Therefore, the final exposure frequencies (EFs) at given RF (and exposure durations) were:

RF	EF (days/year)		
1.0	3 for 1 year		
0.01	100 for 1 year		
0.005	180 for 1 year		
0.001	350 for 2.47 years		
0.0001	350 for 10 years		

These temporal data were entered into Equations 1 and 9 (for every potential exposure route) to calculate the "safe" concentrations of PCBs in carpet for each non-cancer and cancer RF scenario.

## 2.2.4 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario was assumed to be via the incidental ingestion of carpet fibers/dust as a result of the mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to Moya et al. (2004), children consume an average of 193 mg of soil and dust per day. However, the authors also stated that the daily consumption of soil alone is 138 mg/day. Therefore, an average dust ingestion rate of 55 mg/day can be estimated by subtracting 138 mg/day from 193 mg/day. That value was used to approximate the daily fiber ingestion rate (Table 1). A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via digestive tract activities. This factor was set to range from 1% to 100% (Table 1) due to uncertainty as to its real empirical magnitude.

However, please note that oral bioavailability studies show that it is very unlikely that the bioavailability reaches the higher end of the range presented here. Please see the discussion below.

#### 2.2.5 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m³/day, which is the average estimate for children ranging in age from 1 to 10 years old (USEPA, 2000) (Table 1). The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m, and face weight was set to 1,700,000 mg/m² (1.7 kg/m²) based on information obtained from the carpet industry (RPA, 2004; Carpet USA, 2004) (Table 1). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, an air dilution factor (AE) was added to Equation 6. The value of that factor was 8.4 air exchanges per day based on the minimum ventilation rate required by USEPA.

#### 2.2.6 Dermal Uptake Parameters

According to the USEPA (2000), the skin surface area available for contact during warm-weather play of children, with 32% of the total skin surface area exposed, is 2,763 cm²/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact, was estimated at 0.00724 mg/cm² (USEPA, 2000). This value reflects soil adherence for children: post-activity; indoors; and on hands, arms, legs, and feet. An assumption was made that carpet fibers behave similarly to soil particles. The USEPA's default value for the dermal a bsorption factor for tPCBs in soil of 14% (USEPA, 2001) was adopted as the default value in this screening-level risk assessment.

#### 2.3 Hazard and Risk Reference Values

The non-cancer reference dose for PCBs was 0.00002 mg/kg/day (reference dose for Aroclor 1254; USEPA, 2002). The cancer slope factor was 0.07 (mg/kg/day)<sup>-1</sup> and it represented the lowest risk and persistence category recommended by the USEPA (2002). The target risk used in the calculation was the low end of the USEPA's "acceptable risk range" of 1 in 1 million exposed individuals (1 x 10<sup>-6</sup>) (USEPA, 1996, 1997, 2000) (Table 1). The target hazard quotient was set to 1.

#### 2.4 Results and Discussion

For exposures associated with non-cancer hazard, the combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber ranging from approximately 8 to 671 mg tPCBs/kg, depending on the magnitude of the bioavailability and retention factors (Table 2). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in 1 million cancer risk range from 39 to 33,575 mg/kg (Table 2). Comparing the tPCB concentrations estimated in the finished product (carpet; 14.1 mg/kg) to the results from the current assessments suggests that, even at 100% bioavailability and 0% retention, it is highly unlikely that any cancer risk responses will be triggered. Inspection of the results table for non-cancer hazard calculations reveals that the estimated maximum concentration in the final product (14.1 mg/kg) exceeds the acceptable concentrations under only two exposure conditions: when the oral bioavailability is 100% and RFs are 0.001 and 0.0001. Because 100% oral bioavailability is unlikely in actual exposures, these two scenarios should not be of concern in risk-making decisions. This statement is supported by empirical evidence from a recent soil mobilization study of Oomen et al. (2000), who found that the maximum proportion of PCBs that can be digested from PCB-laden soil by a human gut is 40%. Furthermore, the authors indicate that this bioaccessible fraction may not be entirely absorbed by the gut. Also, unlike soil, polypropylene fibers encapsulate PCBs reducing the bioavailability even further. Even if one was to assume 100% absorption of the bioaccessible fraction (i.e. bioavailability factor = 40%) the allowable concentration of PCBs in carpet would be well above the maximum concentration of 14.1 mg/kg. According to our calculations, the absorption factor (a product of bioaccessibility and intestinal absorption) would have to be more than 53% in order for the allowable carpet concentrations to drop below that threshold.

There is one technical point to note in Table 2. The inclusion of the volatilization/source depletion factor actually has its most significant influence on the estimated dose from the ingestion pathway. As a result, the lowest RFs (0.001 and 0.0001) result in the lowest risk-based concentration. This is because the PCBs remain in the carpet longer so that they can be ingested via the carpet dust. In effect, as the RF decreases, the PCBs persist in the carpet fiber longer and the impact of the RF diminishes. This effect can be seen in Table 2 where the acceptable tPCB concentrations at RF=0.001 and RF=0.0001 are almost identical. In consequence, the exposure, dose, and ultimately, the risk are a ttributed a lmost entirely to the ingestion route of exposure. In contrast, at higher RFs (up to 1.0) the PCBs are not retained in the carpet for extended periods of time, and therefore, while the concentration in the air is higher under this condition, it is only for a very short period of time. Therefore, the exposure may be higher, but for a shorter period of time.

Please note that the use of the results of this analysis for risk management decision making should be done with caution because of the level of the uncertainty associated with the estimate of the maximum carpet concentration, retention factor, the quantity of ingested fiber, and oral bioavailability. These factors likely overstate exposure (and therefore risk) for several reasons, not the least of which is the probability that the polypropylene matrix is likely to provide a significant barrier to any encapsulated PCBs. Therefore, given the extensive level of conservatism and the low likelihood of PCBs being 100% bioavailable, it is doubtful that children exposed to carpet would experience any adverse health effects.

# 3. Conclusions

Despite high-end exposure assumptions, the concentrations determined to be within the USEPA's acceptable cancer risk range were well above the maximum concentration of tPCBs estimated in the carpet. Two conservative exposure scenarios for non-cancer hazards (i.e., 100% oral bioavailability at RF=0.001 and RF=0.0001) indicated that the allowable carpet concentrations may be lower than those estimated in the final product. However, given the redundant conservatism built into the assessment (e.g., the low likelihood of 100% oral bioavailability), it is likely that the risks and hazards are substantially overstated. Therefore, the current analysis suggests that there was no unacceptable risk, and that there are no obvious public health concerns associated with the pigments in carpet.

# 4. References

- Clariant (Confidential Business Information undated). Exposure and Toxicological Assessment for PCBs in Multilayered Food Packaging Film. Clariant reviewed document with USEPA in December, 2003.
- 48 Fed. Reg. 50846, November 1, 1983. Inadvertent production of tPCBs in the synthesis of dyes,
- 62 Fed. Reg. 9365, March 3, 1997. Department of Health and Human Services. Food and Drug Administration.
- 21CFR Part 178. Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers. Final Rule.
- BBL (Blasland, Bouck, and Lee). 2004. Conceptual Exposure Model and Preliminary Assessment for End Users of Pigment Red 144 and 214. Blasland Bouck and Lee, August 31, 2004.
- BBL. 2005. Addendum to Report: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, April 11, 2005. Blasland Bouck and Lee, August 4, 2005.
- Bennet, D.H. and E.J. Furtaw. 2004. Fugacity-based indoor residential pesticide fate model. Environ. Sci. Technol. 38: 2142-2152.
- Bigger, A.S. and L.B. Bigger. 2004. Carpet considerations. A new generation of carpet and the equipment to keep it clean gives more cost-effective options. www.facilitiesnet.com. Last accessed November, 2004.
- Carpet USA. 2004. Inventory of carpets available for sale. www.carpet-use.com. Last accessed November, 2004.
- Hack, A. and F. Selenka. 1996. Mobilization of PAH and PCB from contaminated soil using a digestive tract model, Toxicol. Lett. 88: 199-210.
- Long, C.M., H.H. Suh, and P. Koutrakis. 2000. Characterization of indoor particle sources using continuous mass and size monitors. J. Air Waste Manage, Assoc. 50: 1236-1250.
- MacKay, D., W.Y. Shiu, and K.C. Ma. 1992. Illustrated Handbook of Physical-Chemical Properties and Environmental Fate for Organic Chemicals. Volume I. Lewis Publishers, Chelsea, USA, 697 pp.
- Mayes, B.A., G.L. Brown, F.J. Mondello, K.W. Holtzclaw, S.B. Hamilton, and A.A. Ramsey. 2002. Dermal absorption in rhesus monkeys of polychlorinated biphenyls from soil contaminated with Aroclor 1260. Regul. Toxicol. Pharmacol. 35: 289-295.
- Moya, J.B.S., C.F. Bearer, and R.A. Etzel. 2004. Children's behavior and physiology and how it affects exposure to environmental contaminants. Pediatrics 113: 996-1006.
- Murray, D.M. and D.E. Burmaster. 1995. Residential air exchange rates in the United States: Empirical and estimated parametric distributions by season and climatic region. Risk Analysis 15: 459-465.
- Oomen, A., A. Sips, J. Groten, D. Sijm, and J. Tolls. 2000. Mobilization of PCBs and Lindane from soil during in vitro digestion and their distribution among bile salt micelles and proteins of human digestive fluid and the soil. Environ. Sci. Technol. 34: 297-303.

- Qi, Shuang. 2003. PCB Volatilization from Sediments. PhD Thesis, University of Cincinnati, Department of Environmental Engineering. 144p
- RPA (Radiant Panel Association). 2004. Carpet and cushion. Technical notes. Radiant Panel Association. www.radiantpanelassociation.org. Last accessed November, 2004.
- Ruby, M.V., K.A. Fehling, D.J. Paustenbach, B.D. Landenberger, and M.P. Holsapple. 2002. Oral bioaccessibility of dioxins/furans at low concentrations (50-350 ppt toxicity equivalent) in soil. Environ. Sci. Technol. 36: 4905-4911.
- Smiciklas-Wright, H., D.C. Mitchell, S.J. Mickle, A.J. Cook, and J.D. Goldman. 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, pre-publication version, 252 pp.
- USEPA (United States Environmental Protection Avency). 1 989. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A). U.S. Environmental Protection Agency Office of Solid Waste and Emergency Response, Toxics Integration Branch, Washington, DC. EPA/540/1-89/002.
- USEPA (United States Environmental Protection Avency). 1996. PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. EPA/600/P-96/001.
- USEPA (United States Environmental Protection Avency). 1997. Exposure Factors Handbook. General Factors. United States Environmental Protection Agency, Office of Research and Development, Washington, DC. EPA/600/P-95/002Fa.
- USEPA (United States Environmental Protection Avency). 2000. Child-Specific Exposure Factors Handbook. United States Environmental Protection Agency, Office of Research and Development. NCEA-W-0853.
- USEPA (United States Environmental Protection Avency). 2001. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites, Inerim Guidance. OSWER 9355.4-24.
- USEPA (United States Environmental Protection Avency). 2002. Region 9 PRGs Table 2002 Update. United States Environmental Protection Agency, Region 9, San Francisco, CA.
- Won, D.Y., R.L. Corsi, and M. Rynes. 2000. New indoor carpet as an adsorptive reservoir for volatile organic compounds. Environ. Sci. Technol. 34: 4139-4198.

# 5. Tables

Table 1. Exposure and Risk Model Input Parameters

Parameter	Value	Source
General		
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 10 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (maximum; yrs)	10	Bigger and Bigger (2004)
Exposure Duration (years)	I to 10	Calculated <sup>1</sup>
Exposure Frequency (days/year)	3 to 350	Calculated <sup>1</sup> ; USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging time: non-cancer (maximum; days)	365 to 3,650	Calculated <sup>1</sup> ; USEPA (1997; 2002)
Averaging time: cancer (days)	25,550	USEPA (1997; 2002)
Maximum PCB carpet concentration (mg PCB/kg carpet)	14.1	Estimated; Clariant
Total PCB mass (mg) in a hypothetical room	599	Calculated
Ingestion		
Dust (soil) ingestion rate (children; mg dust/day)	55	Moya et al. (2004)
Bioavailability of PCBs in fiber (%)	1, 5, 10, 50, and 100	Assumption
Inhalation .		
Inhalation rate (1 to 10 yrs old; m³/day)	10.4	USEPA (2000)
Complete air exchange rate (1/day)	8.4	USEPA (1995)
Vapor pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Room volume (Hypothetical; m³)	50	Assumption
Floor area (Hypothetical; m²)	25	Assumption
Carpet thickness (m)	0.01286	RPA (2004)
Carpet area mass (face weight; kg/m²)	1.7	Carpet USA (2004)
Room temperature (K)	293	Assumption
Molecular weight of air (g/mol)	29	Calculated
Molecular weight of PCB (g/mol)	292	Calculated
Atmospheric pressure (atm)	1	Assumption
Molar volume of air (cm³/mol)	20.1	Calculated
Molar yolume of PCB (cm³/mol)	268	Calculated
Diffusivity of PCB in air (m²/day)	0.416	Calculated; Fuller et al. (1966) <sup>2</sup>
Vapor pressure of PCB 44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Ideal gas constant (Pa x m³/mol x K)	8.314	Constant
Retention factor (unitless)	0.0001 to 1	Assumption

Parameter	Value	Source	
Dermal			
Dust adherence factor for children post-activity indoors on hands, arms, legs, and feet (mg/cm²)	0.00724	USEPA (2000)	
Contact skin surface area during warm-weather play with 32% skin exposed (cm²/day)	2,763	USEPA (2000)	
Dermal uptake factor	0.14	USEPA (2001)	
Hazard and Risk Reference Values			
Target hazard quotient	1	USEPA (1997; 2002)	
Non-cancer reference dose (mg/kg BW/day)	0.00002	USEPA (2002)	
Cancer slope (mg/kg BW/day) <sup>-1</sup>	0.07	USEPA (2002)	
Target cancer risk	1 x 10 <sup>-6</sup>	USEPA (1997; 2002)	
Target lifetime average daily dose (mg/kg BW/day)	0.000014	Equal to acceptable risk over cancer slope	

 $<sup>{}^{1}</sup>Retention factor-dependent \\ {}^{2}D_{Air} = 10^{\cdot 3}*(t_{Air}{}^{1.75}*(1/M_{Air} + 1/M_{PCB})^{0.5})/P(V_{Air}{}^{0.33} + V_{PCB}{}^{0.33})^{2}$ 

Table 2. August 2006 Revised Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber for Child Non-Cancer and Cancer Risk Scenarios Assuming Complete Volatilization from Carpet Surface and Finite PCB mass

Oral	Accepta	ble Concentrat	ion in Carpet l	Riber (mg tPC	B/kg)
Bioavailability	Retention Factor				
Factor	0.0001	0.001	0.005	0.01	1
		Non-Cancer F	lazard		•
0.01	135.4	133	237	387	671
0.05	81.8	80.9	149	252	653
0.10	54.7	54.3	102	176	632
0.50	15.0	15.0	28.8	51.2	501
1,00	7.87°	7.86ª	15.2	27.2	398
		Cancer R	isk		
0.01	677	2,686	11,855	19,374	33,575
0.05	409	1,636	7,456	12,616	32,665
0.10	274	1,099	5,094	8,785	31,595
0,50	75.0	303	1,441	2,562	25,034
1.00	39.3	159	760	1,359	19,875

<sup>&</sup>lt;sup>a</sup>The result is 14.2 mg/kg for oral bioavailability factor of 0.53